Summary of Safety and Effectiveness K002941

Encore Orthopedics®, Inc.
9800 Metric Blvd
Austin, TX 78758
512-832-9500

DEC - 4 2000

Trade Name: Acetabular Plates

Classification Name: Hip joint metal/polymer/metal semi-constrained cemented prosthesis

Description: The Acetabular Plates is a series of five cages and comes in sizes 52-66mm in 4mm increments with three hole and four hole versions. Each plate has three iliac flanges positioned superiorly and one ischial hook inferiorly that provides supplemental screw fixation and attachment to the ilium and ischium, respectively. These components, once positioned in the acetabulum and attached to the ilium and ischium, provide structural integrity to an otherwise structurally compromised joint. The improved acetabular construct gained by attaching the device provides a much better site for implantation of the functional acetabular bearing surface.

The Acetabular Plates is fabricated from commercially pure Titanium that conforms to ASTM F67. The outside surface corrundum blasted to give a roughened surface.

Intended Use: The indications for use of the Acetabular Plates in reconstruction of the hip joint due to disease, deformity or trauma. The devices are indicated for use in skelatally mature individuals undergoing primary and/or secondary revision surgery. .

Comparable Features to Predicate Device(s): Features comparable to predicate devices include same materials, design and indications as the Biomet TI-MAX PROTRUSIO CAGE (K001376) and the Osteonics GAP II Restoration Acetabular Shells (K980774).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 4 2000

Mr. J. D. Webb
Vice President Research & Development
Encore Orthopedics, Inc.
9800 Metric Boulevard
Austin, Texas 78758

Re: K002941
Trade Name: Acetabular Plates
Regulatory Class: II
Product Code: LWJ
Dated: September 19, 2000
Received: September 21, 2000

Dear Mr. Webb:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Mark N Milhorn

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K002941

Device Name: Acetabular Plates

Indications For Use:

Acetabular Plates
Indications For Use

The indications for use of the Acetabular Plates in reconstruction of the hip joint due to disease, deformity or trauma. The devices are indicated for use in skelatally mature individuals undergoing primary and/or secondary revision surgery. The Acetabular Plates are to be used in conjunction with any commercially available polyethylene cup.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use Yes (per 21 CFR 801.109) OR Over-The-Counter Use No

(Optional Format 1-2-96)

for Mark N Milhous

(Division Sign-Off)
Division of General Restorative Devices

510(k) Number K002941